

Eur J Vasc Endovasc Surg 34, 291–298 (2007)

doi:10.1016/j.ejvs.2007.05.013, available online at <http://www.sciencedirect.com> on  ScienceDirect

A Modular Aortouniiliac Endovascular Stent-graft is a Useful Device for the Treatment of Symptomatic and Ruptured Infrarenal Abdominal Aortic Aneurysms: One-year Results from a Multicentre Study

R.J. Hinchliffe, ^{*} B.D. Braithwaite and European BiFab Study Collaborators^a

Department of Vascular and Endovascular Surgery, Nottingham University Hospital, Nottingham, UK

Introduction. Endovascular repair (EVAR) of acute symptomatic and ruptured abdominal aortic aneurysm (rAAA) can be difficult without a large stock of suitable graft sizes. We report a prospective European multicentre study of a modular aortouniiliac stent-graft.

Patients and methods. Seven centres, with elective EVAR experience, participated in the study. Sixty-five patients were enrolled from September 2002 – April 2005. Some 45 patients had rAAA and 20 were acutely symptomatic. Their median age was 74 (69–80.3) years, 49 (75%) were men. From a choice of 4 body and 4 limb sizes, stent-grafts were deployed under local or general anaesthesia.

Results. The endovascular delivery system was introduced and the aneurysm excluded from the circulation in a median of 40 (30–60) minutes from the first incision.

The median operative duration was 150 (120–190) mins, blood loss 300 ml (200–800). 33 (51%) operations were performed by a vascular surgeon alone.

There were a total of 4 (6%) peri-operative re-interventions, endovascular ($n=1$), open ($n=2$) and thrombectomy ($n=1$). The peri-operative mortality in the rupture group was 40% and 10% in the symptomatic group.

Conclusions. Aortouniiliac stent-grafts provide rapid exclusion of rAAA. Suitably trained surgeons can do the operation without a radiologist's support. The mortality rate from rAAA treated with EVAR remains high.

© 2007 Published by Elsevier Ltd on behalf of European Society for Vascular Surgery.

Keywords: Aortic aneurysm; AAA; Ruptured AAA; Symptomatic AAA; EVAR.

Introduction

Several hospitals have published their experience with endovascular repair (EVAR) of ruptured abdominal aortic aneurysms (rAAA). Despite encouraging results, the proportion of patients with rAAA being treated by EVAR remains low.¹ This may be because of logistical problems including the availability of an experienced endovascular team and a sufficient stock of suitable grafts.

To enable EVAR for rAAA, it has been suggested that endovascular stent-grafts must be immediately available in a wide range of sizes. This would require a large stock of bifurcated stent-grafts and may not, for financial and storage reasons be possible in most vascular units.

A stent-graft designed for rAAA should achieve rapid haemorrhage control and, given the emergent nature of the disease, be straightforward to deploy, and require a minimum of endovascular expertise.

The objective of this study was to determine the safety and performance of a modular aortouniiliac endovascular stent-graft, (Cook Europe, Bjaereskov, Denmark), for the treatment of acute symptomatic and ruptured infra-renal abdominal aortic aneurysms.

Methods

The study was an open multicentre study, with seven participating European centres. (see acknowledgments).

All of the participants were experienced with the Zenith[®] aortic stent-graft for elective EVAR. They received training in deployment of the experimental system.

Patient enrolment started in September 2002 and continued until May 2005. Patients aged more than 50 years, with an acute symptomatic (abdominal or back

^{*}Corresponding author. R. J. Hinchliffe, Department of Vascular and Endovascular Surgery, E Floor, West Block, Nottingham University Hospital, Derby Road, Nottingham NG7 2UH, UK.

E-mail address: robhinchliffe@hotmail.com

^a See acknowledgements for European BiFab Study Collaborators.

pain of less than 48 hours duration) or those with a ruptured AAA confirmed by contrast enhanced computed tomographic angiography (CTA) were eligible for enrolment. Patients had to meet all the inclusion and exclusion criteria (Fig. 1). Each centre received local ethics committee approval. Where possible, patients provided written or verbal consent for study entry.

The participating vascular units were provided with a total of four proximal stent-graft components (22, 26, 30 and 34 mm diameter), four distal stent-graft components (12, 16, 20, 24 mm distal diameter) and two 'over the wire' occluding plugs (16, 24 mm diameter). The main body and iliac limb lengths were

a standard 130 mm and 100 mm long respectively. The components had a 12 mm junction so that the distal limb could be inserted into the proximal body. The length of the deployed graft could therefore be varied between 130 mm and 205 mm. If patients required a longer graft then a 12 mm diameter stent could be inserted between the two components.

All patients had pre-operative spiral CTA. The operations were performed by a vascular surgeon or interventional radiologist (or both) depending upon local experience. The type of anaesthesia (local or general anaesthetic) was left at the discretion of the operating surgeon. The main body of the stent-graft

Inclusion criteria

The patients must have met the following criteria before entering the study:

1. The patient is 50 years or older.
2. The patient has a Ruptured Aneurysm (retroperitoneal haematoma +/- extravasation of contrast on contrast CT) or an Acute Symptomatic Aneurysm (<48 hours) of the infrarenal, abdominal aorta.
3. Anatomical criteria for Acute Symptomatic Aneurysm
 - a. Location of lesion:
 - I. Infrarenal segment of the abdominal aorta
 - II. Length from the lowest renal artery to the aneurysm sac >10 mm
 - b. Aneurysm size:
 - I. Length of proximal, aneurysm neck/fixation site >10 mm
 - II. Aneurysm neck <32 mm diameter
 - III. External iliac artery diameter \geq 7 mm
4. Anatomical criteria for ruptured aneurysm:

If the surgeon estimates that there is a good chance of aneurysm exclusion.

5. Patient's informed consent is obtained. A witnessed verbal consent is permissible for ruptured cases, whereas written consent is required for acute, symptomatic cases.

Exclusion criteria

Exclusion of patients was always left to the discretion and judgment of the investigators of the participating centres. If there is a questionable contraindication, the Principal Investigator has to be consulted.

In the treatment of patients with ruptured aneurysms, the morphological assessment of suitability is left to the discretion of the operating surgeon (given the broad guidelines).

1. Anatomical criteria, from CTA scan:
 - a. Location of lesion: aneurysm less than 10 mm below renal arteries
 - b. Aneurysm neck diameter \geq 32 mm
 - c. External iliac artery diameter <7 mm
2. The patient is suffering from an acute life-threatening illness other than the aortic disease to be treated with the Zenith® Endovascular Graft.
3. Pregnancy
4. Anaphylactic reaction to contrast media
5. Allergy to stainless steel or polyester
6. Inability to obtain informed consent

Fig. 1. Study entry criteria.

was deployed first followed by the iliac limb extension (ipsilateral iliac artery), which was 'trombosed' inside the main body according to the length required. The stent-grafts were oversized by 4–6 mm in the proximal aortic neck and 2–3 mm in the iliac artery. After deployment of the aortouniliac stent-graft an occluding plug was deployed in the contralateral common iliac artery. If the contra-lateral common iliac had a diameter greater than 22 mm then a larger occluding device was used (Endomed, Endomed Inc, Phoenix, AZ). The procedure was completed with a femoro-femoral bypass graft to restore flow to the contra-lateral femoral artery. At the end of the procedure all patients had intra-operative 'completion angiography' to determine whether the aneurysm had been excluded.

A detailed account of the deployment sequence of the Zenith stent-graft is given elsewhere.² One of the perceived advantages of the aortouniliac device was the absence of the need for cannulation of a short limb of the graft.

The efficacy of the experimental stent-graft was determined by patient outcome at 1 month, 3 months, 6 months and 12 months. The primary endpoint was patient survival at 1 month. Patients were followed up with clinical examination and CTA. An independent data monitor assessed the validity of data received from each hospital.

Outcome data were divided into patients treated for symptomatic AAA and those treated for rAAA.

Patients

A total of 65 patients were enrolled in the study between September 2002 and May 2005 (Nottingham ($n = 33$); Truro ($n = 5$); Bournemouth ($n = 5$); Ostrava-Vitkovice ($n = 11$); Stockholm ($n = 2$); San Sebastian ($n = 7$); Plzen ($n = 2$)). Procedures were performed by a team of vascular surgeon and interventional radiologist in 32 (49%) patients. The remainder were treated by a vascular surgeon alone.

Some 45 patients (69%) were treated for ruptured AAA and 20 (31%) for acute symptomatic AAA. The mean age of patients in the ruptured group was 76.6 (range 60–91) years and 75.5 (67–85) in the symptomatic group. Thirty-three (73%) and 16 (80%) were male in the respective groups. Some five patients (11%) in the rupture group and eight (40%) in the acute symptomatic group had previously had open ($n = 4$) or endovascular repair ($n = 9$) of their abdominal aortic aneurysm.

The ASA distribution is given in Table 1. The Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) risk-factor score

Table 1. ASA distribution of patients

ASA class	Rupture $n = 45$ (%)	Symptomatic $n = 20$ (%)
I	0 (0)	0 (0)
II	2 (4)	4 (20)
III	6 (13)	9 (45)
IV	22 (49)	5 (25)
V	15 (33)	2 (10)

was also used.³ The median SVS-ISCV risk score was 4 (2–7) in the rupture group and 7 (4–10) in the acute symptomatic group. Thirty eight percent of patients in both groups had a history of cardiovascular disease. Some 21% of patients with ruptured AAA and 23% of acute symptomatic patients had pulmonary disease.

Pre-operative haematological and biochemical analyses were similar between groups (Table 2). Ruptured aneurysms were larger than their symptomatic counterparts (Table 3).

The most commonly used main body sizes were the two largest diameters, 34 mm ($n = 22$) and 30 mm ($n = 13$) (Table 4). A total of five patients required an additional 12 mm iliac limb to act as a bridging piece to meet the required aortoiliac length (ruptured $n = 3$; symptomatic $n = 2$).

Four patients required body extensions ($n = 2$) or Palmaz stents (Palmaz P4014 stent, Cordis Endovascular, Warren, NJ, USA) ($n = 2$) to fully exclude the aneurysm. These are discussed below.

Six (13%) of the ruptured cases were sufficiently stable to be done under regional anaesthesia (Table 5).

Results

Ruptured AAA

There were no intra-operative deaths. A total of 14 (31%) patients died in the rupture group within 30 days. Some six patients died within 24 hours of

Table 2. Pre-operative haematological and biochemical analysis

	Rupture median (iq range)	Symptomatic median (iq range)
WBC ($\times 10^3/\text{mm}^3$)	12.5 (10.7–16.6)	8.7 (7.1–9.8)
Platelets ($\times 10^3/\text{mm}^3$)	166 (128–225)	231 (193–292)
Hematocrit (%)	33.0 (27.0–38.6)	41.0 (38.3–42.4)
Hb (g/dL)	11.0 (9.4–12.5)	13.7 (12.5–14.3)
Prothrombin time (sec)	12.0 (10.5–17.0) [§]	11.7 (10.9–14.6)
Partial thromboplastin time (sec)	31.5 (25.1–45.9) [#]	30.5 (28.6–31.7) [★]
Glucose	7.8 (6.6–10.4) [*]	6.6 (4.5–8.7) [†]
Urea	7.6 (6.6–10.9)	6.4 (4.5–8.7)
Creatinine	132 (109–176)	110 (94–126)

^{*} Data available in $n = 19$ patients; [†] $n = 10$; [§] $n = 35$; ^{||} $n = 15$; [#] $n = 30$; [★] $n = 14$.

Table 3. Pre-operative aneurysm morphology

Morphology (mm)	Rupture (median, iq range)	Symptomatic (median, iq range)
AAA diameter	85 (72–96)	75 (59–87)
Supra-renal diameter	25 (22–28)	25 (21–26)
Neck length	25 (18–35)	22 (19–30)
Neck diameter	26 (22–28)	24 (21–26)
Renal artery to aortic bifurcation	130 (118–144)	120 (112–130)
Proximal neck to aneurysm angle	40 (30–80) [¥]	72 (54–115) [∞]
Calcification of proximal neck	†	§
None	16	8
Scattered	15	10
Two-thirds of the circumference	1	0
Circumferential	0	0
Thrombus at proximal neck	*	
None	19	5
Scattered	10	8
Two-thirds of the circumference	2	5
Circumferential	0	0
Right common iliac artery diameter	16 (12–21)	16 (12–20)
Left common iliac artery diameter	14 (12–21)	16 (10–20)
Right common iliac artery length	50 (40–57)	59 (53–66)
Left common iliac artery length	50 (40–60)	60 (50–60)
Right external iliac artery diameter	9 (8–10)	10 (9–11)
Left external iliac artery diameter	9 (8–10)	11 (10–12)

[¥] Data available in 17 patients ($n = 17$); [∞] $n = 11$; [†] $n = 32$; [§] $n = 18$; * $n = 31$; || $n = 18$.

operation. One patient died from a ruptured common iliac artery. They had an uncomplicated deployment of the aortouniiliac graft. Review of the pre-operative CTA showed that the iliac artery was the site of the

Table 4. Stent-graft sizes used

Device used	Ruptured ($n = 45$)	Symptomatic ($n = 20$)
Zenith Rupture Body*		
ZRB – 22 mm	3	0
ZRB – 26 mm	12	5
ZRB – 30 mm	15	8
ZRB – 34 mm	16 ¹	6
Zenith Rupture Leg		
ZRL – 12 mm	13	4
ZRL – 16 mm	12	3
ZRL – 20 mm	8	7
ZRL – 24 mm	11	5
Iliac Plug [‡]		
ZIP – 16 mm	12	9
ZIP – 24 mm	19	8
ESP-20-20 [†]	1	0
Endomed 36 mm	1	0
Endomed 40 mm	0	1
Leg Extension		
TFLE-12-88	1	1
TFLE-20-88	1	0
TFLE-18-71	0	1
ELSE-16-55	1	0

¹ One ZRB-34 used as extension to create aneurysm seal.

[†] Previous generation occluder (not an over the wire system).

* Data missing on one patient with symptomatic aneurysm.

[‡] In one symptomatic patient no occluder was required due to pre-operative iliac artery occlusion. Data were not available in another symptomatic patient. In the rupture group, one iliac artery was occluded pre-op and another patient was converted to open repair. Data were missing in a total of 10 patients.

Table 5. Intra-operative data

	Rupture (%) median (iq range)	Symptomatic (%) median (iq range)
Anesthesia type		
General	30 (67)	12 (60)
Regional	6 (13)	8 (40)
Local	9 (20)	0 (0)
Stent-graft deployment (minutes)	30 (20–45) [#]	50 (30–60) ~
Fluoroscopy (minutes)	18 (14–28) [¥]	21 (17–25) [°]
Duration of procedure (minutes)	150 (120–180)	158 (120–213)
Contrast volume (ml)	150 (133–200)	190 (146–268)
Number requiring blood products	29 (64)	7 (35)
Blood loss (ml)	425 (200–825)	200 (100–500) [§]
Replaced blood volume (ml)	1400 (600–2000)*	600 (400–925) [†]

[#] Data available in $n = 36$ patients; ~ $n = 17$; [¥] $n = 22$; [°] $n = 12$; ^{||} recorded in $n = 32$; [§] recorded in $n = 17$; * In $n = 20$ patients receiving transfusion (median 600 ml (0–1500) in all rAAA patients); [†] In 7 patients receiving transfusion (median 0 ml (0–400) in all symptomatic patients).

original rupture and the stent graft had not covered the lesion. The iliac artery rupture was not recognised intra-operatively or on completion angiography (Table 6).

Two patients suffered bilateral renal artery occlusion. One of these was intentional. The patient was already on dialysis for chronic renal failure and presented with rupture. He had unfavourable aneurysm morphology with a short neck but was offered EVAR on compassionate grounds. The stent-graft was placed across both renal artery ostia to seal the aneurysm. The other patient had no further intervention and was started on haemodialysis.

A total of eight patients had internal iliac artery occlusion, four of which were in the ruptured group. None of the occlusions were bilateral. Three were deliberate and necessary to adequately seal off blood flow to the aneurysm.

One patient with rAAA required conversion to open repair because the stent-graft was pulled into the aneurysm sac. Another patient with rAAA developed intra-operative stent-graft thrombosis. Their operation was converted to an axillo-bifemoral graft.

The causes of death for the other 8 patients who died following rAAA repair (>24hours but within

Table 6. Intra-operative complications

Complication	Ruptured	Symptomatic
Bilateral renal artery occlusion	2	2
Internal iliac artery occlusion	4	4
Stent-graft thrombosis	1	0
Iliac artery rupture	1	0
Stent-graft migration	1	0

30 days) were multiple organ failure (MOF) (4), acute renal failure (2), myocardial infarction (1) and respiratory failure (1).

A further four patients died in hospital after 30 days giving a total 30-day and in-hospital mortality of 40% (18) for the rupture group. Of the four deaths in hospital after 30 days, one patient died of gastric cancer on day 92. The cancer presented with gastrointestinal bleeding post-operatively. Another patient died on day 34 as a result of a perforated duodenal ulcer. A patient died as the result of aspiration pneumonia from an enteral feeding tube (day 39). A fourth patient died on day 62 from chest infection and respiratory failure. He had a history of severe COAD and exacerbation pre-operatively.

A number of patients had peri-operative adverse events (Table 7). One patient with a rAAA developed abdominal compartment syndrome. The most common systemic complications in those undergoing rAAA repair were pulmonary (38%) and renal (36%). The number of peri-operative adverse events was far higher in those undergoing rAAA repair (57 versus 6). Some required additional endovascular and open procedures.

Following rAAA repair there was one type I leak which was detected 12 hours post-operatively when the patient became haemodynamically unstable. The patient was taken back to the operating theatre and had a laparotomy and placement of peri-aortic bands around the aortic neck. On review, the patient had placement of an undersized stent-graft. The stent-graft had been sized using intra-operative calibration angiography because of a poor quality pre-operative CT. A 22 mm stent-graft was placed in a 22 mm aortic neck. Completion angiography had not revealed an endoleak.

There were 5 type II endoleaks which were left without intervention.

In the rupture group three patients died after discharge from hospital. One died at 9 weeks from

a type A thoracic aortic dissection and another died of congestive cardiac failure at 6 months. There was one aneurysm related death, from sepsis (20 weeks). The source of the sepsis was the aortic pseudoaneurysm that had been treated by EVAR.

During follow-up (post 30-days), Two of the 3 type II endoleaks in the ruptured group sealed spontaneously. There were no type I or type III endoleaks detected during follow up.

There were two open interventions required in the rAAA group but no endovascular intervention. One patient required incision and drainage of a groin abscess (no evidence of graft infection). The patient who had required EVAR of a ruptured aortic pseudoaneurysm needed percutaneous drainage of an abscess.

Acute symptomatic AAA

In the symptomatic group, the 30-day mortality was 5% (1). This patient died on day 4 from multiple organ failure. A second patient in this group died in-hospital from acute renal failure on day 33 giving a 30-day and in-hospital mortality of 10% (2).

There were two bilateral renal artery occlusions. One patient underwent mesentero-renal bypass and another was converted to open repair.

One patient in the symptomatic group required a thrombectomy for an occluded femoro-femoral bypass graft.

Two endoleaks were detected in the symptomatic group. One CTA detected type I endoleak was treated successfully by placement of a main body extension piece and Palmaz stent 5 days after the first operation. There was also one type 2 endoleak which was observed.

There were two late deaths in the symptomatic group. One patient died from the complications of chronic renal failure at 7 months. This patient was on dialysis prior to EVAR. Another died from oesophageal cancer at 8 months.

In the symptomatic group three patients developed claudication (one had buttock claudication because of an internal iliac artery (IIA) occlusion). In the rupture group one patient had intermittent claudication (both IIAs were patent), one had a wound abscess, one patient developed sepsis and three patients developed neurological complications. One developed an epidural haematoma following epidural anaesthetic. Of the other two patients, one had femoral nerve neuralgia requiring medical treatment and another developed foot drop (IIA occlusion).

During follow-up there were no open secondary interventions required in the symptomatic group but

Table 7. Peri-operative adverse events

Peri-operative Adverse Event	Rupture (n = 45)	Symptomatic (n = 20)
Systemic complications		
Cardiac	9	1
Cerebral	2	0
Pulmonary	17	0
Renal	16	1
Gastrointestinal	5	1
Haematological	2	0
Other	1	0
Peripheral neurological complications	3	0
Access site complications	2	2
Ischaemic complications	1	1

three patients required endovascular intervention. Two patients received coil embolisation of type II endoleaks (4 and 5 months post-operatively). Another patient had angioplasty of an external iliac stenosis for the treatment of intermittent claudication (11 months).

Discussion

The modular aortouniiliac stent-graft system was proposed for elective EVAR in 1997.⁴ It was suggested that a modular aortouniiliac comprising 16 components could replace a total of 750 unitary bifurcated systems. The Nottingham group further developed this concept.⁵ Others have adopted a similar stent-graft system for the management of rAAA.⁶

This study has demonstrated that an 'off the shelf' aortouniiliac stent-graft can be used to repair acute symptomatic and ruptured AAA. In this multi-centre European study by seven experienced endovascular centres the peri-operative mortality rates compared favourably with those published for conventional open repair.⁷ This was a selected study population, where many patients had been turned down for conventional elective open repair.

One of the limitations of the emergency endovascular technique is the need for an endovascular team. Use of an aortouniiliac system reduced the need for some of the skills required to perform elective EVAR. Specifically those required to swiftly cannulate the short limb of a bifurcated graft. Many vascular units have insufficient radiologists to provide an emergency endovascular service.⁸ In this study, appropriately trained vascular surgeons treated half of the patients without a radiologist being present in the operating room. The surgeons had not had traditional radiology training.

One advantage of the aortouniiliac system may be the speed of haemorrhage control. Bifurcated systems require catheterisation of the stent-graft and placement of a contralateral iliac limb before the rAAA can be excluded from the circulation. This manoeuvre can take time even in experienced hands.

In this trial it was possible to achieve rapid aneurysm exclusion in the majority of patients. The median time to exclusion of rAAA was 30 minutes (Table 5).

However it took 150 (median) minutes to perform the operation. In a contemporary series from an experienced centre using bifurcated stent-grafts (Zenith, Cook) in selected patients with ruptured AAA, the mean operating time was 110 minutes.⁹ The increased time in this study was probably related to

the cross-over graft component of the operation. Other techniques may achieve more rapid aneurysm control. These include aortic occlusion balloons or the percutaneous delivery of the stent-graft. Neither technique was used in this series. Percutaneous placement of an aortouniiliac system is possible but surgical exposure of the femoral arteries is required to fashion the femoro-femoral bypass.

In this study the larger diameter main body components were used more frequently (30 mm, 34 mm). This was not a surprising finding as it has already been demonstrated that large aneurysms usually have large diameter necks.¹⁰ The advantages of an aortouniiliac system were exemplified by the two patients who had ectatic contralateral iliac arteries. If a bifurcated system had been used then the device would have been deployed in the external iliac artery, risking continued AAA perfusion via a patent internal iliac artery. In these two patients large occluding plugs were used (36 mm and 40 mm Endomed, Endomed Inc, Phoenix, AZ). The durability of these devices has not been published. Both plugs successfully occluded the common iliac artery up to one-year follow-up.

The facility for 'tromboning' of the aortouniiliac device made it possible to treat the longer renal artery to aortic bifurcation distance found in rAAA. The median renal artery-aortic bifurcation distance in the ruptured group was 130 mm and common iliac artery 50 mm. Some AAA were so long that five patients (rAAA, $n=3$, symptomatic $n=2$) needed a 12 mm extension piece to fully exclude the aneurysm.

One stent-graft was not sufficiently oversized in the aortic neck. This problem was encountered in a patient with a poor pre-operative CTA scan and measurements were done using intra-operative calibration angiography. The resulting endoleak and secondary open intervention (peri-aortic ligatures) emphasised the importance of good pre-operative CTA.

There were several complications that resulted directly from operator error. One stent-graft was deployed too proximally occluding both renal arteries. Three major complications (2 bilateral renal artery occlusions and one migration) were encountered during retrieval of the delivery system. It is vital to visualize the docking procedure of the top cap with the delivery system. Failure to do so resulted in the graft migrating cranially occluding both renal arteries in two patients whilst in another the supra-renal stent was caught during cap retrieval and the whole stent-graft was dragged into the aneurysm sac. The operating surgeon did not adequately visualise the latter procedure using fluoroscopy.

The device and operator errors may not have been surprising because of the emergent nature of surgery

and adverse aneurysm morphology. Complications can occur with open repairs. In one study of open surgery over a 10-year period, the rate of vascular complications following rAAA repair was double that seen during elective repair (17% versus 8%).¹¹

In this study patients were followed up for one year. Previous studies on open rAAA repair suggested that patients continued to die up to one year post-operatively from the lingering effects of the rupture and peri-operative physiological insults.¹¹ This did not appear to be the case in the present study. Only the patient with an infected pseudoaneurysm suffered an aneurysm related death after 30 days.

One of the risks of emergency surgery might be inadequate planning of the graft and subsequently a high secondary intervention rate. In the rupture group there were a total of four (9%) (two early, two late) re-interventions during the follow-up period of one year. These results are similar to the U.K. EVAR 1 trial.¹² In that trial the secondary intervention rate for elective EVAR was approximately 10% at one year. This suggests there were no more complications in the mid-term with patients who had aortouniliac EVAR for ruptured AAA when compared with their elective counterparts.

Despite the endovascular approach there were a significant number of systemic adverse events in patients with rAAA, notably pulmonary in 38% (17) and renal in 36% (16). The incidence of pulmonary complications is reasonable when compared with results after open repair of rAAA, however, the incidence of renal complications is similar.¹³ Although some of these complications are inevitable in critically ill patients with rupture, it may be possible to reduce their incidence by refining the endovascular technique.

Only one patient developed the abdominal compartment syndrome. However, pulmonary complications were the most common systemic complication following EVAR. Some authors have demonstrated the feasibility of repair of ruptured aneurysms using local anaesthesia and sedation.⁹ A recent analysis of the EUROSTAR database of patients undergoing elective EVAR found no significant difference (2.2% -v- 1%) in pulmonary complications between those undergoing general ($n = 3848$) or local anaesthesia ($n = 310$).¹⁴ Indeed, it carries some potential drawbacks including patient discomfort and movement artefact. The local anaesthetic technique usually requires a bifurcated stent-graft system. The requirement for a femoro-femoral cross-over graft makes this difficult and consequently it was only possible to perform EVAR under total local anaesthesia in nine (14%) cases.

In this series there were three (6%) cases of peripheral neurological damage, three times the incidence noted following open repair.¹³ Buth and colleagues have demonstrated significant rates of paraplegia following EVAR of ruptured AAA, particularly when associated with occlusion of one or both internal iliac arteries.¹⁵

Further work is required to identify those patients with symptomatic and rAAA who will be best treated by EVAR compared with open repair. This study has shown that the modular aortouniliac stent-graft will be a useful tool for the vascular specialist.

Acknowledgements

^aEuropean BiFab Study Collaborators:

Mr. B.D. Braithwaite, Mr. S.T.R. MacSweeney, Dr. S.C. Whitaker, Mrs. S. Spencer, Nottingham University Hospital, Nottingham, UK;
Dr. S. Travis and Mr. K. Woodburn, Royal Cornwall Hospital, Truro, Cornwall, UK;
Mr. S. Parvin, Mr. S. Darke, Dr. T.S. Creasy, Royal Bournemouth Hospital, Bournemouth, UK;
Dr. V. Prochazka, Centrum Vascular Intervention, Ostrava-Vitkovice, Czech Republic;
Dr. L. Blohme and Dr. Kalin, Karolinska University Hospital, Stockholm, Sweden;
Dr. M. De Blas and Dr. J.M. Egana, Hospital De Gipuzkoa, Sebastian, Spain;
Dr. B. Kreuzberg, Prof. V. Treska, University Hospital Plzen, Plzen, Czech Republic.

Cook Europe provided the stent grafts and paid each unit a fee for data collection.

The Study was independently monitored by Clinimetrics Research Europe Ltd, Maidenhead, Berks, U.K. who verified all the presented data by examination of patient notes and clinical record folders.

References

- 1 LEON Jr LR, LABROPOULOS N, LAREDO J, RODRIGUEZ HE, KALMAN PG. To what extent has endovascular aneurysm repair influenced abdominal aortic aneurysm management in the state of Illinois? *J Vasc Surg* 2005;41:568–574.
- 2 LAWRENCE-BROWN M, SIEUNARINE K, HARTLEY D, VAN SCHIE G, GOODMAN MA, PRENDERGAST FJ. The Perth HLB bifurcated endoluminal graft: a review of the experience and intermediate results. *Cardiovasc Surg* 1998;6:220–225.
- 3 RUTHERFORD RB, BAKER JD, ERNST C, JOHNSTON KW, PORTER JM, AHN S *et al.* Recommended standards for reports dealing with lower extremity ischaemia. *J Vasc Surg* 1997;26:517–538 (Erratum, *J Vasc Surg* 2001;33:805).
- 4 ARMON MP, YUSUF SW, WHITAKER SC, GREGSON RH, WENHAM PW, HOPKINSON BR. The anatomy of abdominal aortic aneurysms:

- implications for sizing of endovascular grafts. *Eur J Vasc Endovasc Surg* 1997;**13**:398–402.
- 5 HINCHLIFFE RJ, YUSUF SW, MACIEREWICZ JA, MACSWEENEY ST, WENHAM PW, HOPKINSON BR. Endovascular repair of ruptured abdominal aortic aneurysm—a challenge to open repair? Results of a single centre experience in 20 patients. *Eur J Vasc Endovasc Surg* 2001;**22**:528–534.
 - 6 PEPPELENBOSCH N, ZANETTI S, BARBIERI B, BUTH J, ERA study collaborators. Endograft treatment in ruptured abdominal aortic aneurysms using the Talent AUI stentgraft system. Design of a feasibility study. *Eur J Vasc Endovasc Surg* 2004;**27**:366–371.
 - 7 BOWN MJ, SUTTON AJ, BELL PR, SAYERS RD. A meta-analysis of 50 years of ruptured abdominal aortic aneurysm repair. *Br J Surg* 2002;**89**:714–730.
 - 8 ASHLEIGH RJ, BUTTERFIELD JS, ASQUITH J, CHALMERS N, MURPHY G. A cross-site vascular radiology on-call service: the Manchester experience. *Clin Radiol* 2005;**60**:389–393.
 - 9 VERHOEVEN EL, PRINS TR, VAN DEN DUNGEN JJ, TIELLIU IF, HULSEBOS RG, VAN SCHILFGAARDE R. Endovascular repair of acute AAAs under local anesthesia with bifurcated endografts: a feasibility study. *J Endovasc Ther* 2002;**9**:729–735.
 - 10 HINCHLIFFE RJ, ALRIC P, ROSE D, OWEN V, DAVIDSON IR, ARMON MP *et al.* Comparison of morphologic features of intact and ruptured aneurysms of infrarenal abdominal aorta. *J Vasc Surg* 2003;**38**: 88–92.
 - 11 CHO JS, GLOVICZKI P, MARTELLI E, HARMSSEN WS, LANDIS ME, CHERRY Jr KJ *et al.* Long-term survival and late complications after repair of ruptured abdominal aortic aneurysms. *J Vasc Surg* 1998;**27**:813–819.
 - 12 EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. *Lancet* 2005;**365**:2179–2186.
 - 13 GLOVICZKI P, PAIROLERO PC, MUCHA Jr P, FARNELL MB, HALLETT Jr JW, ILSTRUP DM *et al.* Ruptured abdominal aortic aneurysms. Repair should not be denied. *J Vasc Surg* 1992;**15**:851–857.
 - 14 RUPPERT V, LEURS LJ, STECKMEIER B, BUTH J, UMSCHIED T. Influence of anesthesia type on outcome after endovascular aortic aneurysm repair: an analysis based on EUROSTAR data. *J Vasc Surg* 2006;**44**:16–21.
 - 15 PEPPELENBOSCH N, CUYPERS PW, VAHL AC, VERMASSSEN F, BUTH J. Emergency endovascular treatment for ruptured abdominal aortic aneurysm and the risk of spinal cord ischemia. *J Vasc Surg* 2005;**42**:608–614.

Accepted 27 May 2007

Available online 10 July 2007